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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

421/34/2

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on 10/17/2005

Signature Amy Yost

Typed or printed name Amy Yost

Application Number

09/998,058

Filed

November 30, 2001

First Named Inventor

David W. Threadgill

Art Unit

1634

Examiner

Sakelaris, Sally A

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 39,395

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Arles A. Taylor, Jr.
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10-17-2005
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

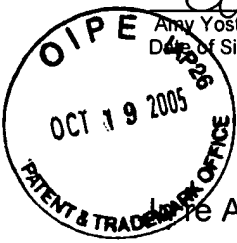
☐ *Total of 1 forms are submitted.

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PATENT


Amy Yost
Date of Signature October 17, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of: Threadgill *et al.*

Group Art Unit: 1634

Serial No.: 09/998,058

Examiner: Sakelaris, Sally A.

Filed: November 30, 2001

Docket No.: 421/34/2

Confirmation No.: 6701

For: METHOD FOR ULTRA-HIGH RESOLUTION MAPPING OF GENES AND DETERMINATION OF GENETIC NETWORKS AMONG GENES UNDERLYING PHENOTYPIC TRAITS

APPLICANTS' STATEMENT IN SUPPORT OF THE
PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

Claims 1-27, 46-53, and 671-74 are pending in U.S. Patent Application Serial No. 09/998,058 (hereinafter "the '058 Application"). All pending claims have been rejected on one or more bases as presented in the Final Official Action dated June 16, 2005 (hereinafter "the Final Official Action"). Applicants respectfully submit that none of the rejections presented in the Final Official Action are supported by the references cited by the United States Patent and Trademark Office (hereinafter "the Patent Office"), as set forth in more detail hereinbelow.

The 102(b) Rejection over Diehl

Claims 1-10, 15, 19-27, 46-53, 64-73, and 75 have been rejected under 35 U.S.C. § 102(b) over Diehl *et al.* (1997) *Proc. Natl. Acad. Sci. USA* 94:5231-5236 (hereinafter "Diehl"). Applicants respectfully submit that the rejection suffers from the following errors:

- (1) Diehl does not disclose "renewable" populations as recited in claims 1, 46, 64, and 75.

The Conference Panel is respectfully directed to pages 12-13 of Amendment D, filed March 7, 2005, wherein applicants have indicated that a “renewable” population is a population for which every genome can be regenerated.

- (2) Diehl does not disclose “genetically diverse” individuals as recited in claims 1, 46, 64, and 75.

The Conference Panel is respectfully directed to pages 13-14 of Amendment D, filed March 7, 2005, wherein applicants have indicated that the recombinant inbred strains disclosed in Diehl are not “genetically diverse” as that phrase is used in the claims of the ‘058 Application.

Summarizing points (1) and (2), while the Patent Office states on page 4 of the Final Official Action that Patent Office interprets the claims using the “broadest reasonable interpretation”, this broadest reasonable interpretation must be consistent with the specification. The interpretations asserted by the Patent Office are inconsistent with the specification. The Patent Office’s approach to claim interpretation is believed to be error, and when properly interpreted, it is clear that Diehl does not anticipate claims 1-10, 15, 19-27, 46-53, 64-73, and 75.

- (3) Page 4 of the Official Action states: “AXB and BXA recombinant inbred (RI) lines derived from crosses between A/J and C57BL6/J strains were supplied by M. Nesbitt and the mice were then bred by intercrossing recombinant inbred lines...”.

The Conference Panel is respectfully directed to pages 14-15 of Amendment D, filed March 7, 2005, wherein applicants have indicated that the recombinant inbred strains disclosed in Diehl are maintained by crossing members of the same line to each other. An “intercross” is defined as “the mating of individuals that are each heterozygous at a selected genetic loci” (see Specification at page 13). Since RI lines are homozygous at every locus, crossing a male from an RI line to a female of the same line is not an intercross, and only by breeding an RI line to itself, which is not in intercross, can the line be maintained.

Summarily, Diehl does not disclose each and every element of claims 1-10, 15, 19-27, 46-53, 64-73, and 75, and thus does not support a rejection under 35 U.S.C. § 102(b).

The 102(b) Rejection over Bellamy

Claims 1-4 have been rejected under 35 U.S.C. § 102(b) over Bellamy *et al.*, 1991 (*Human Genetics* 87:341-347; hereinafter "Bellamy"). Applicants respectfully submit that the rejection suffers from the following errors:

- (1) The Patent Office has interpreted the term "mapping" in a way that is inconsistent with the way the term is used by one of ordinary skill in the art

The Conference Panel is respectfully directed to pages 18-19 of Amendment D, filed March 7, 2005, wherein applicants have pointed out the errors in the Patent Office's assertions concerning "mapping" in Bellamy.

- (2) Band sharing is not a "phenotype" as that term is understood by one of ordinary skill in the art

The Conference Panel is respectfully directed to pages 19-20 of Amendment D, filed March 7, 2005, wherein applicants have pointed out that the band sharing disclosed in Bellamy is not a phenotype.

- (3) The band sharing disclosed in Bellamy is not modulated by any locus.

The Conference Panel is respectfully directed to page 20 of Amendment D, filed March 7, 2005, wherein applicants have discussed "modulation" by genetic loci and how Bellamy does not identify any genetic loci that modulate any phenotype.

Summarily, the Patent Office's reliance on Bellamy to support the instant rejection is improper because Bellamy does not identify any locus that modulates any phenotype as recited in claims 1-4.

The 103(a) Rejection over Diehl in view of Dindzans and Hedrich

Claims 11-14, 16-18, and 64-73 have been rejected under 35 U.S.C. § 103(a) over Diehl in view of Dindzans *et al.* (1986) *J. Immunol* 137:2355-2360; hereinafter "Dindzans"), and further in view of Hedrich (1981) Genetic Monitoring, Chapter 8 in The Mouse in Biomedical Research, volume I (hereinafter "Hedrich").

The Conference Panel is respectfully directed to pages 21-26 of Amendment D, filed March 7, 2005. These pages detail how the cited combination does not disclose or suggest the use of heterozygous individuals.

Applicants respectfully submit that the combination of Diehl, Dindzans, and Hedrich does not support the rejection of claims 11-14, 16-18, and 64-73 under 35

U.S.C. § 103(a). Summarily, the errors in the Patent Office's interpretation of Diehl is presented hereinabove. Dindzans does not cure these deficiencies, and in fact teaches against the use of heterozygous (*i.e.*, genetically diverse) individuals.

Additionally, the Patent Office misinterprets Dindzans to support the statement on page 10 of the Final Official Action that Dindzans "teach that multiple parents are necessary for the breeding of mice in an attempt to map genes". Applicants respectfully submit that "multiple parents" does not equate to genetic diversity as appears to be asserted by the Patent Office. For example, page 12 of the Final Official Action states that Dindzans teaches that multiple progenitors were used to establish their population for the expected benefit that using multiple progenitors creates a 'unique assortment of parental genes' which is 'useful for the mapping of genes and restriction sites and in the elucidation of mechanisms of genetic control'." Applicants respectfully submit that Dindzans generated its RI lines from only 2 non-recombinant inbred lines (A/J and C57).

Furthermore, applicants respectfully submit that the Patent Office's reliance on Hedrich is misplaced. First, the Patent Office asserts on page 13 of the Final Official Action that "Hedrich's teaching of 8-10 breeding pairs makes obvious the use of at least 3, 4, or 8 non-recombinant parent lines of Dindzans" is conclusory and does not provide any reasonable discussion as to how Hedrich's 8-10 breeding pairs would suggest that the use of multiple non-recombinant parent lines would be beneficial.

Additionally, the proposition that the use of 8-10 breeding pairs in Hedrich renders obvious generating genetically diverse individuals from 3, 4, or 8 non-recombinant inbred lines ignores the clear disclosure in Hedrich that all the members of the foundation colony (FC), pedigreed expansion colony (PEC), and production colonies (PC) were members of the same non-recombinant inbred line, and that the breeding strategies were designed not to generate genetic diversity but to destroy it (*i.e.* to eradicate "deviant alleles"). Thus, it cannot be said that Hedrich would motivate the skilled artisan to generate genetic diversity in a population.

And finally, with respect to the instant rejection as applied to claim 64-73, the cited combination does not disclose or suggest a method of identifying a genetic locus that modulates a phenotype in a panel of cell lines that express the phenotype, since

the references rely on the recombinant inbred strategy for gene mapping which would be inapplicable to a panel of cell lines, which are not recombinant inbred individuals.

SUMMARY

The Patent Office has not presented a *prima facie* case of anticipation of claims 1-10, 15, 19-27, 46-53, 64-73, and 75 over Diehl because Diehl does not disclose genetically diverse individuals. The Patent Office has not presented a *prima facie* case of anticipation of claims 1-4 over Bellamy because Bellamy does not disclose genome mapping or identifying a genetic locus that modulates a phenotype through the mapping step. The Patent Office has not presented a *prima facie* case of obviousness of claims 11-14, 16-18, and 64-73 over Diehl in view of Dindzans, and further in view of Hedrich because the combination does not disclose or suggest employing 3, 4, or 8 non-recombinant inbred lines to establish recombinant inbred strains (claims 11-14 and 16-18) and because the references do not disclose or suggest mapping genes that modulate a phenotype in cells of a panel of cell lines that express the phenotype.

Accordingly, applicants respectfully submit that claims 1-10, 15, 19-27, 46-53, 64-73, and 75 are in condition for allowance. Applicants respectfully request a Notice of Allowance for claims 1-10, 15, 19-27, 46-53, 60-73, 74, and 75, since the Final Official Action indicated that claims 60-63 and 74 were allowed.

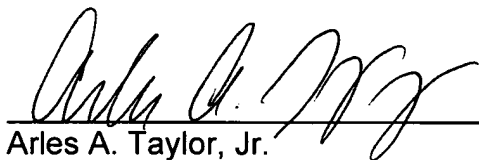
Respectfully submitted,

JENKINS, WILSON & TAYLOR, P.A.

Date:

10/17/2005

By:



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